K051617

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MAR 6 2006

510(k) Summary 12/29/05

NovaBone Putty - Resorbable Bone Void Filler

1. Submitter Information:

Name:	NovaBone Products, LLC
Address:	13709 Progress Boulevard, #33 Alachua, FL 32615
Telephone:	(386) 462-7660
Facsimile:	(386) 418-1636
Contact:	David M. Gaisser

2. Name of Device:

Trade Name:	NovaBone Putty – Resorbable Bone Void Filler
Common Name:	Osteoconductive Bone Void Filler Synthetic Resorbable Bone Graft Material
Classification Name:	Unknown

3. Legally Marketed Predicate Device:

Predicate #1:	NovaBone – Resorbable Bone Graft Substitute [K021336]
Predicate #2:	NovaBone-AR – Resorbable Bone Graft Substitute [K041613]

4. Device Description

NovaBone Putty is a two-component resorbable bone void filler composed of a synthetic bioactive glass particulate mixed with a binder. The major component is a melt-derived calcium-phosphorus-sodium-silicate (Bioglass) particulate designed specifically for its absorbability and osteoconductive nature. The second component is gelatin powder, selected for its biocompatibility and physical gelation properties to act as a temporary binding agent for the particulate. The gelatin is rapidly absorbed from the graft site to permit tissue infiltration between the Bioglass particles and replacement of the particles by host bone during the healing process.

5. Intended Use

NovaBone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous

defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

6. Technological Characteristics

The technological characteristics of NovaBone Putty and the predicate devices NovaBone and NovaBone-AR are similar. All are designed as osteoconductive space-filling particulate devices to be gently packed into defect sites and used as non-structural scaffolds for the body's natural healing and bone regeneration process. To meet this design, the three devices are similar in nature, all being particulate, synthetic, inorganic, biocompatible and osteoconductive materials.

The NovaBone predicate is a single-phase bioactive glass (45S5 Bioglass) particulate device, while the NovaBone-AR is a two-component bioactive glass device, the major phase being the same Bioglass component as in the NovaBone device. The primary component of NovaBone Putty is this same particulate bioactive glass. The main technological difference between NovaBone Putty and the predicate devices is that while the predicates contain only particulate bioactive glass components, the NovaBone Putty device contains a second component that acts as a temporary binding agent between the particles when wetted with water. When wetted, the gelatin component hydrates and fills the space between the particles, resulting in a soft malleable putty to aid product handling and placement. The gelatin binder then is rapidly removed from the implantation site via normal physiologic processes.

For all three devices, the materials are substantially absorbed within the six-month timeframe normally associated with bone remodeling, the devices being replaced by new bone tissue. The gelatin binder of the NovaBone Putty is more soluble than the Bioglass particulate, being rapidly removed from the site to permit space for cell infiltration and bone formation.

7. Warnings and Precautions

NovaBone Putty does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth. In cases of fracture fixation or where load support is required, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

NovaBone Putty is intended for use by clinician familiar with bone grafting and internal/external fixation techniques. NovaBone Putty must not be used to gain screw purchase or to stabilize screw placement.

NovaBone Putty contains gelatin. This device should not be used by individuals having known allergies to gelatin products.

8. Complications

Possible complications are the same as to be expected of autogenous bone grafting procedures. These may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

The potential for allergic reaction to the gelatin component exists.

9. Conclusion

NovaBone Putty is claimed to be substantially equivalent to the NovaBone and NovaBone-AR predicates as a non-structural osteoconductive bone void filler for osseous defects. *In vivo* performance data were presented. Additional supporting *in vitro* data were supplied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2006

Mr. David M. Gaisser
Director, Operations
NovaBone Products, LLC
13709 Progress Blvd., #33
Alachua, Florida 32615

Re: K051617
Trade/Device Name: NovaBone Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler devices
Regulatory Class: Class II
Product Code: MQV
Dated: December 29, 2005
Received: January 3, 2006

Dear Mr. Gaisser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark M. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K051617

Device Name: NovaBone Putty - Resorbable Bone Void Filler

Indications For Use:

NovaBone Putty - Resorbable Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use XX OR (Per 21 CFR 801.109) Over-The-Counter Use ____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051617